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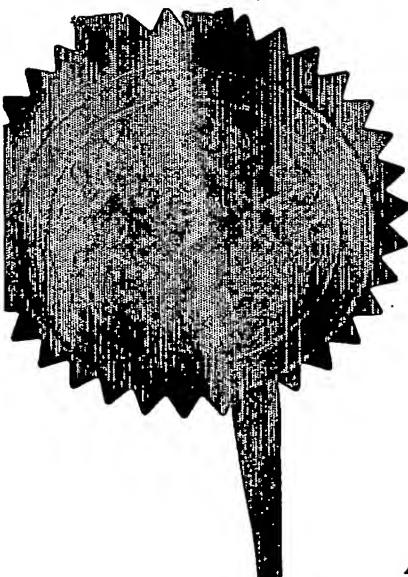
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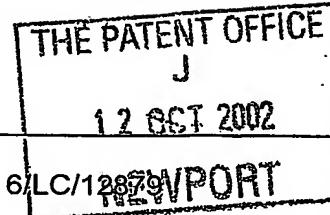
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Dated 4 November 2003

Request for grant of a patent

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1. Your reference



The Patent Office

Cardiff Road
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2. Patent application number
(The Patent Office will fill in this part)

0223827.7

12 OCT 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Bernard SAMS
22 Avondale Avenue
London N12 8EJ
United Kingdom

Stephen SAMS
51 Brunswick Grove
New Southgate
London N11 1ED
United Kingdom

348302(001)

848347(001)

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

PACKAGING FOR A BLISTER PACK

5. Name of your agent (if you have one)

Sanderson & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent (including postcode)

34 East Stockwell Street
Colchester
Essex
CO1 1ST

Patents ADP number (if you know it)

1446001

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Country Priority application number (if you know it) Date of filing (day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing (day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

No

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.

See note (d))

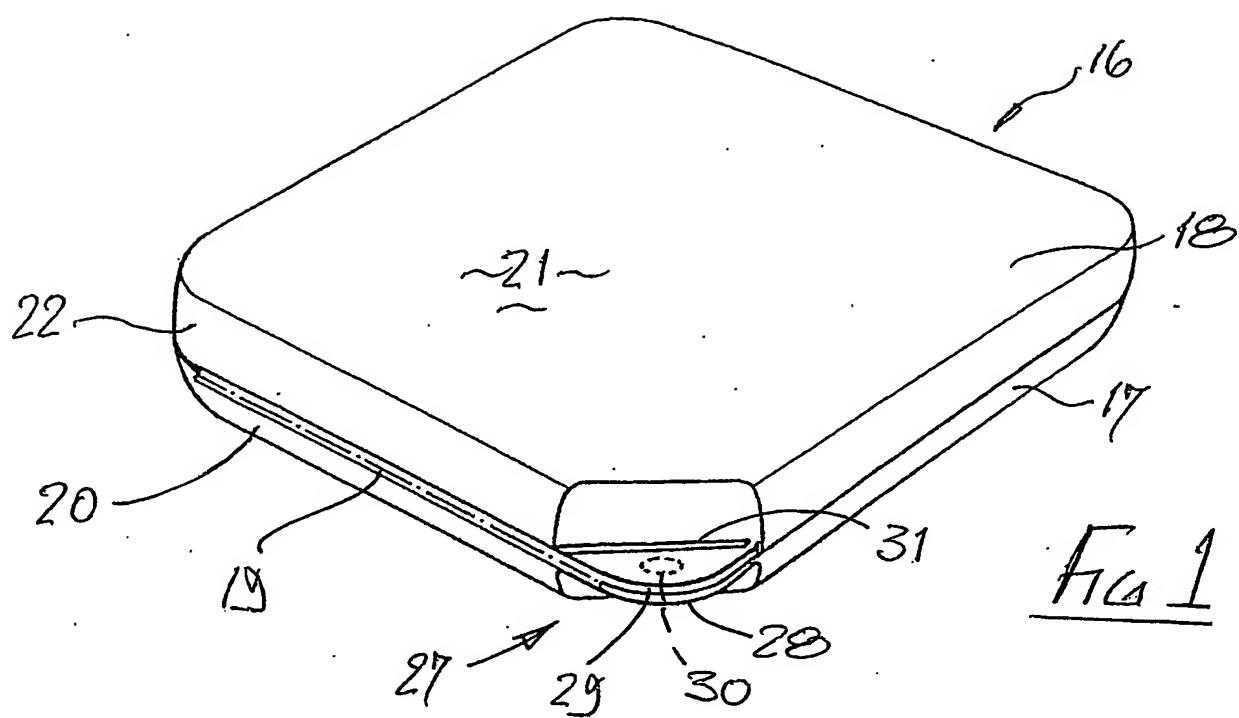


Fig 1

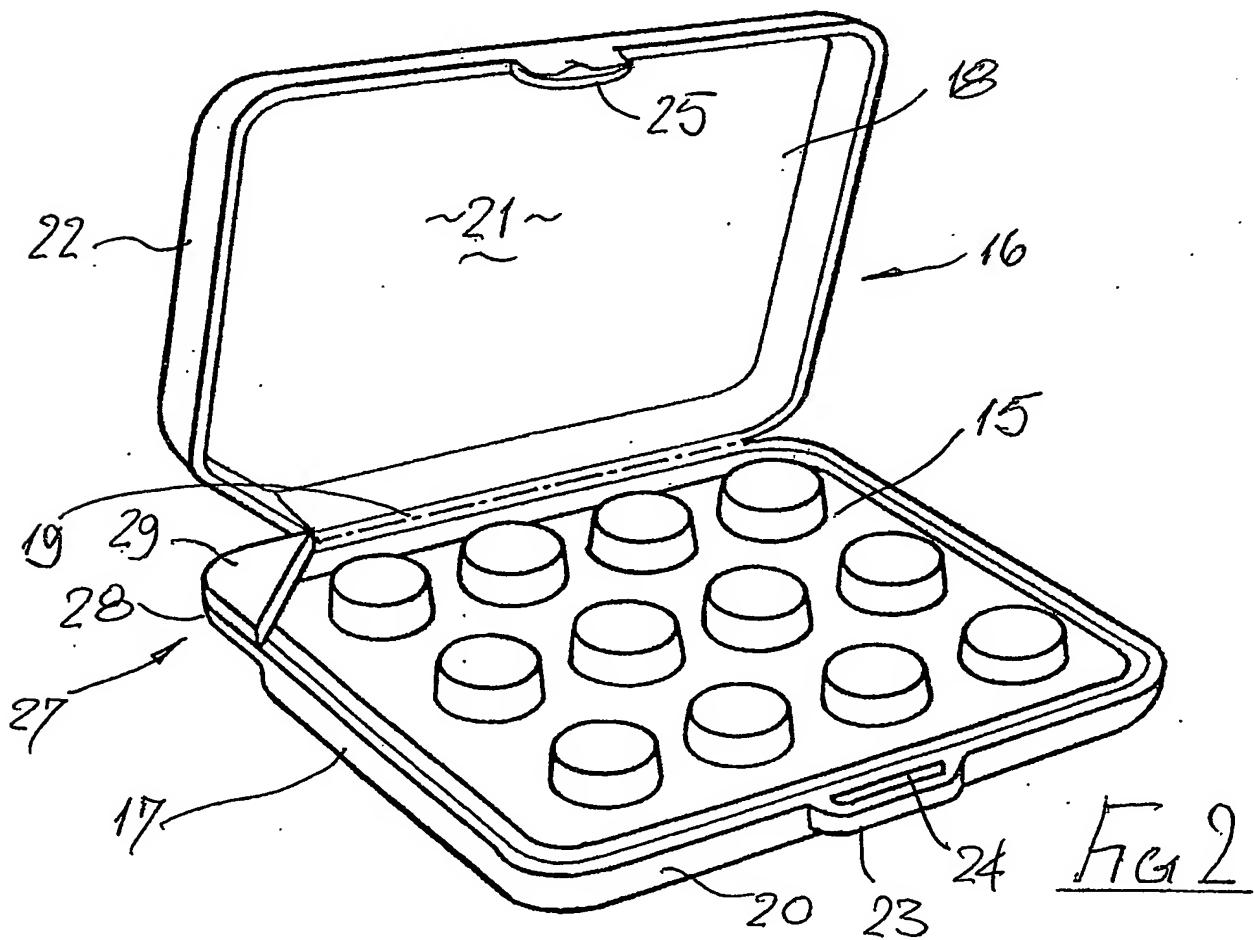
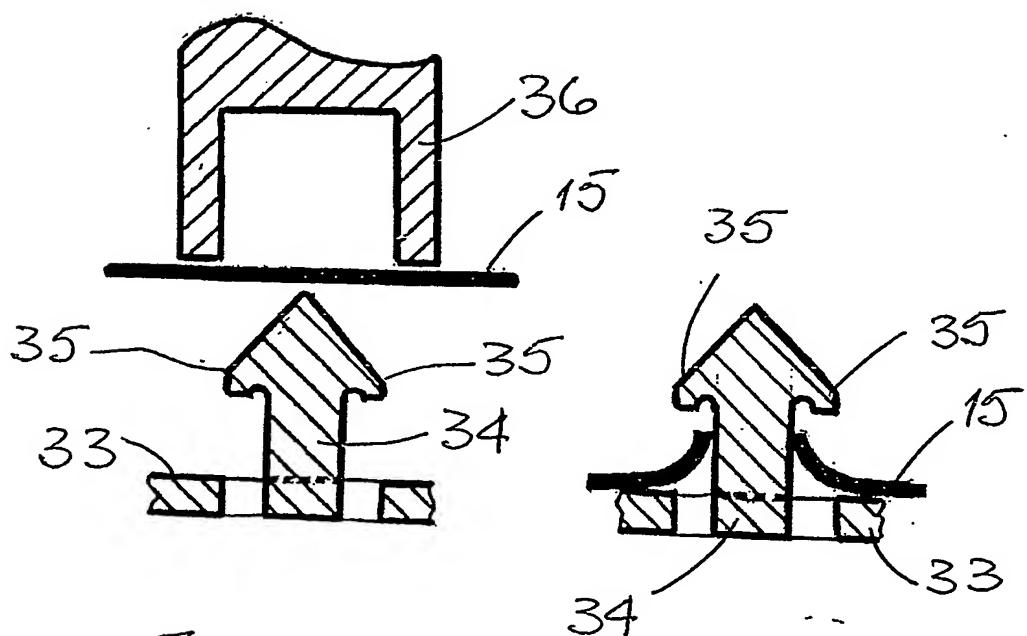
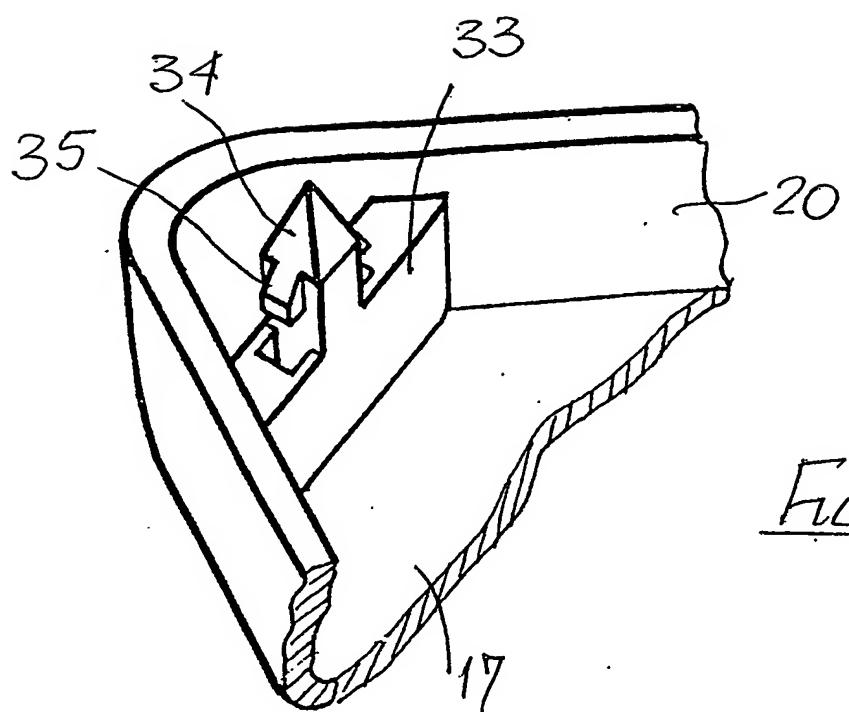
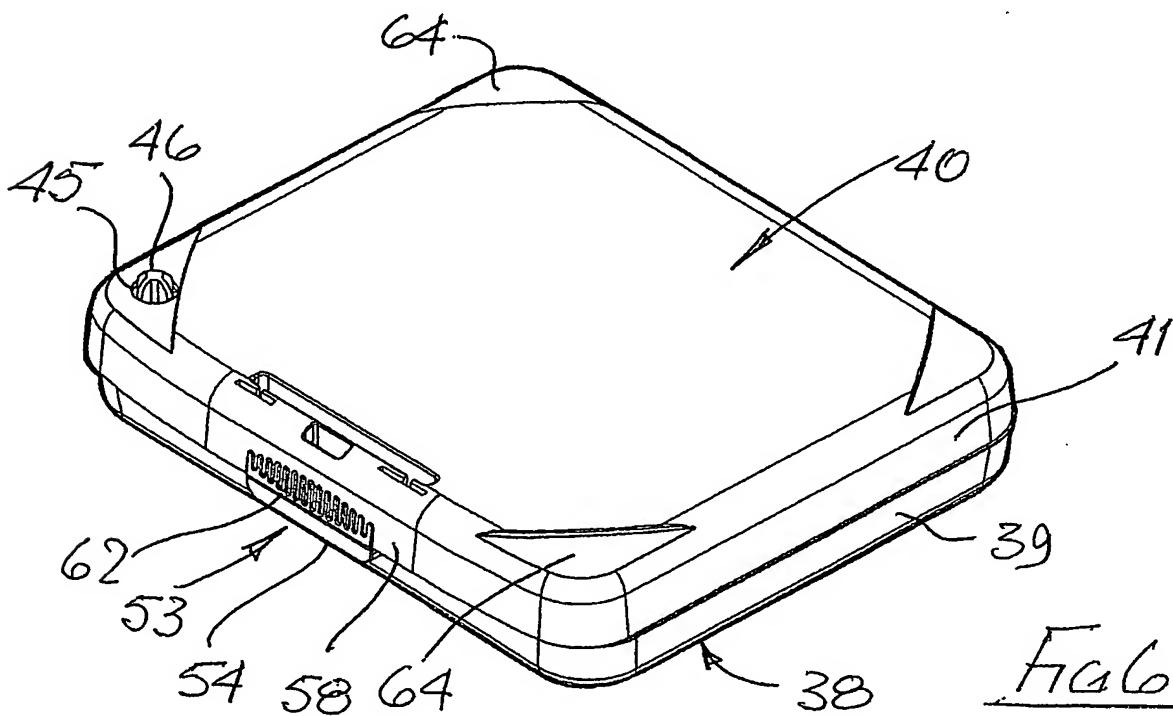
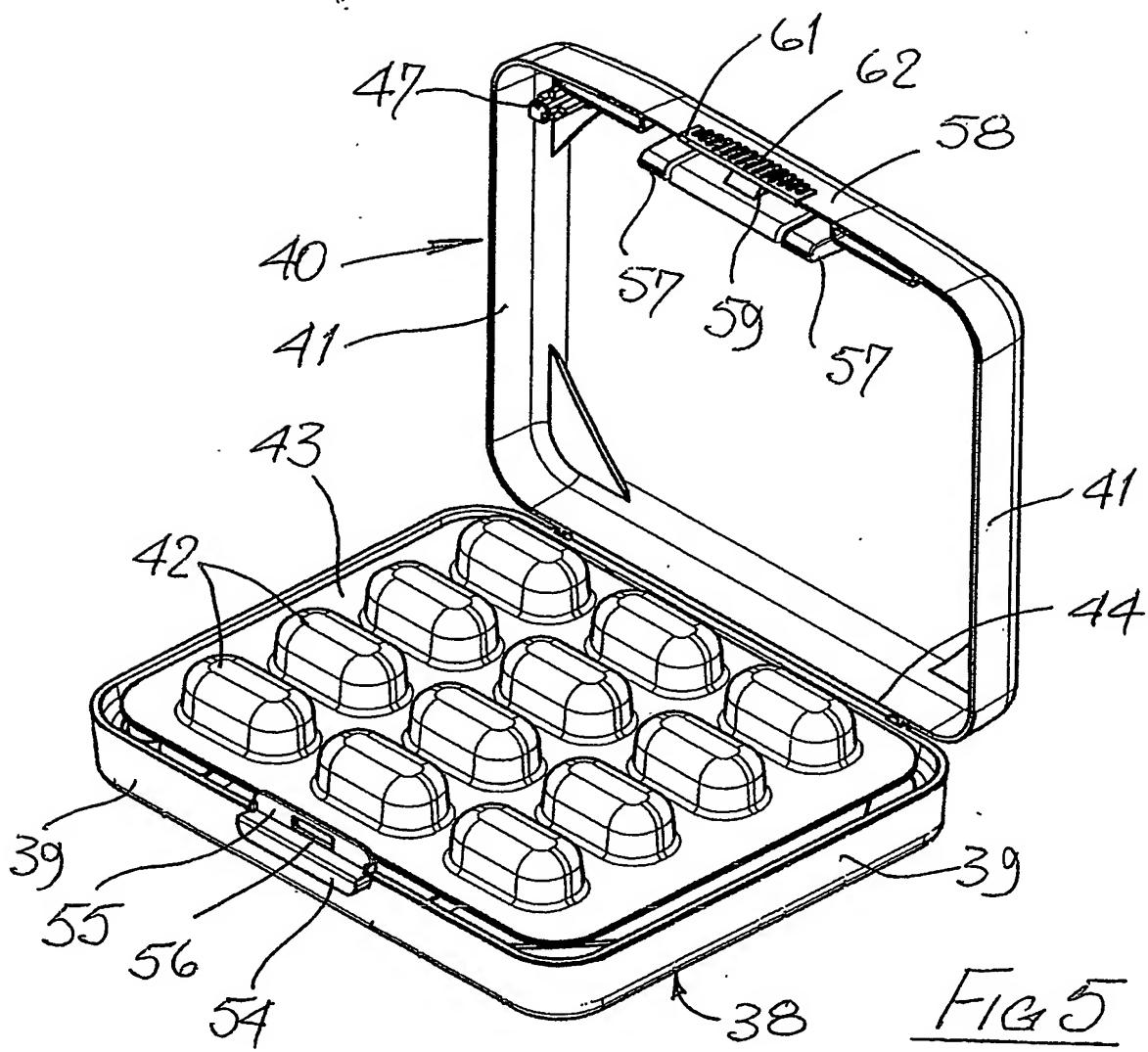
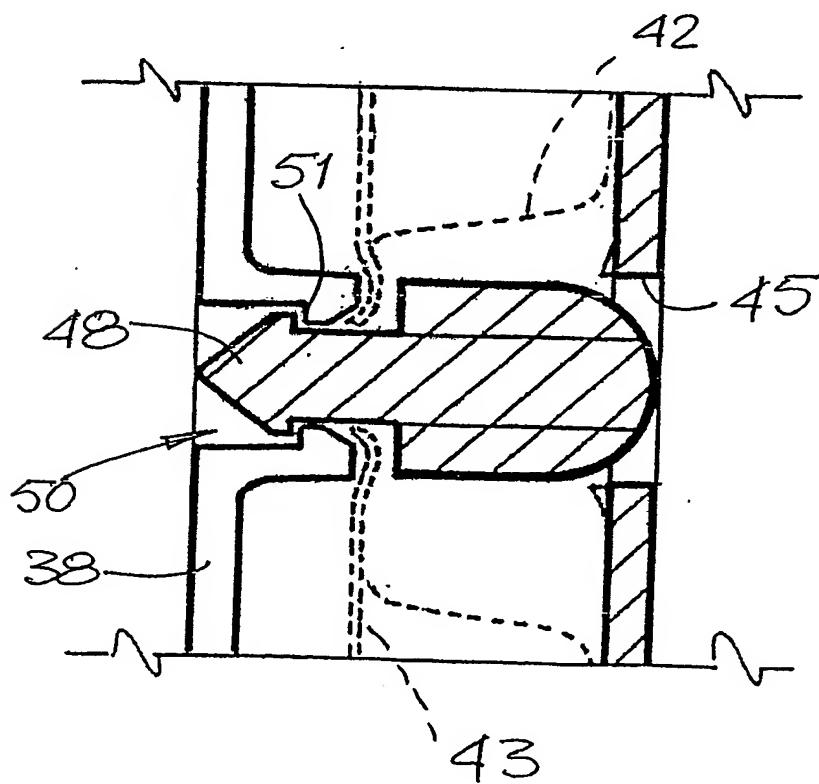
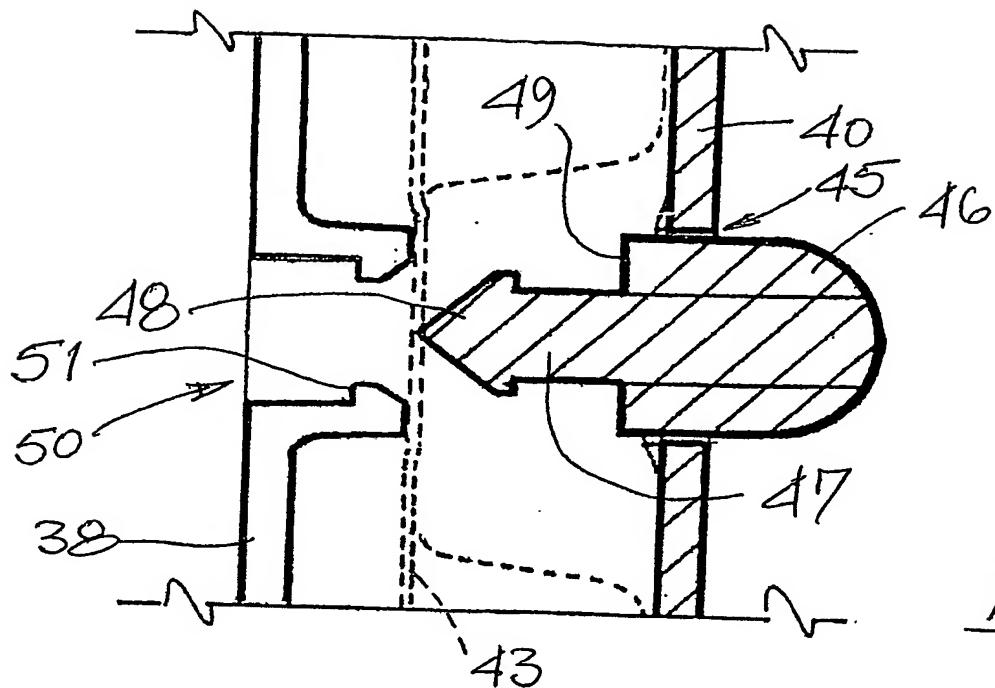


Fig 2







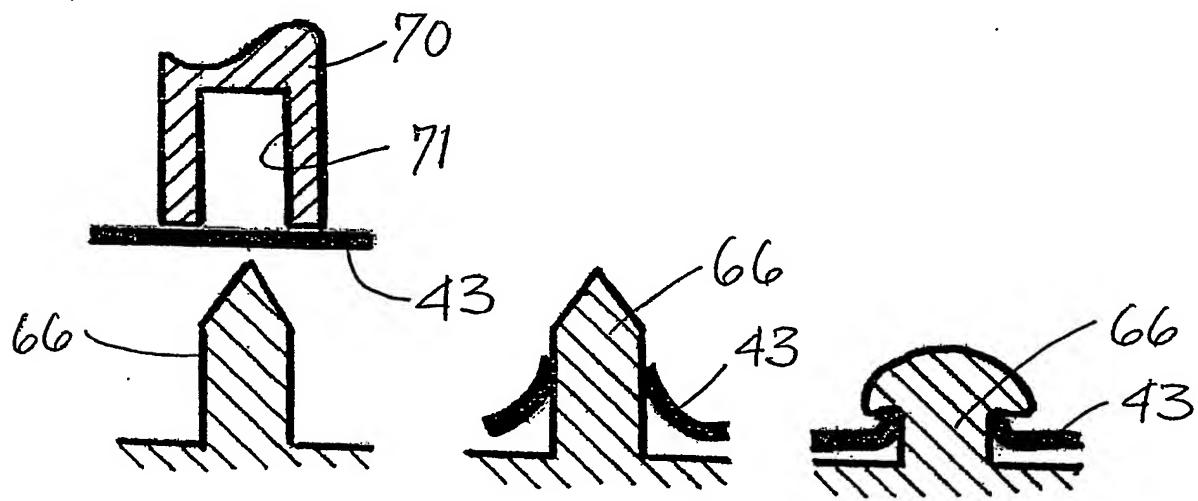
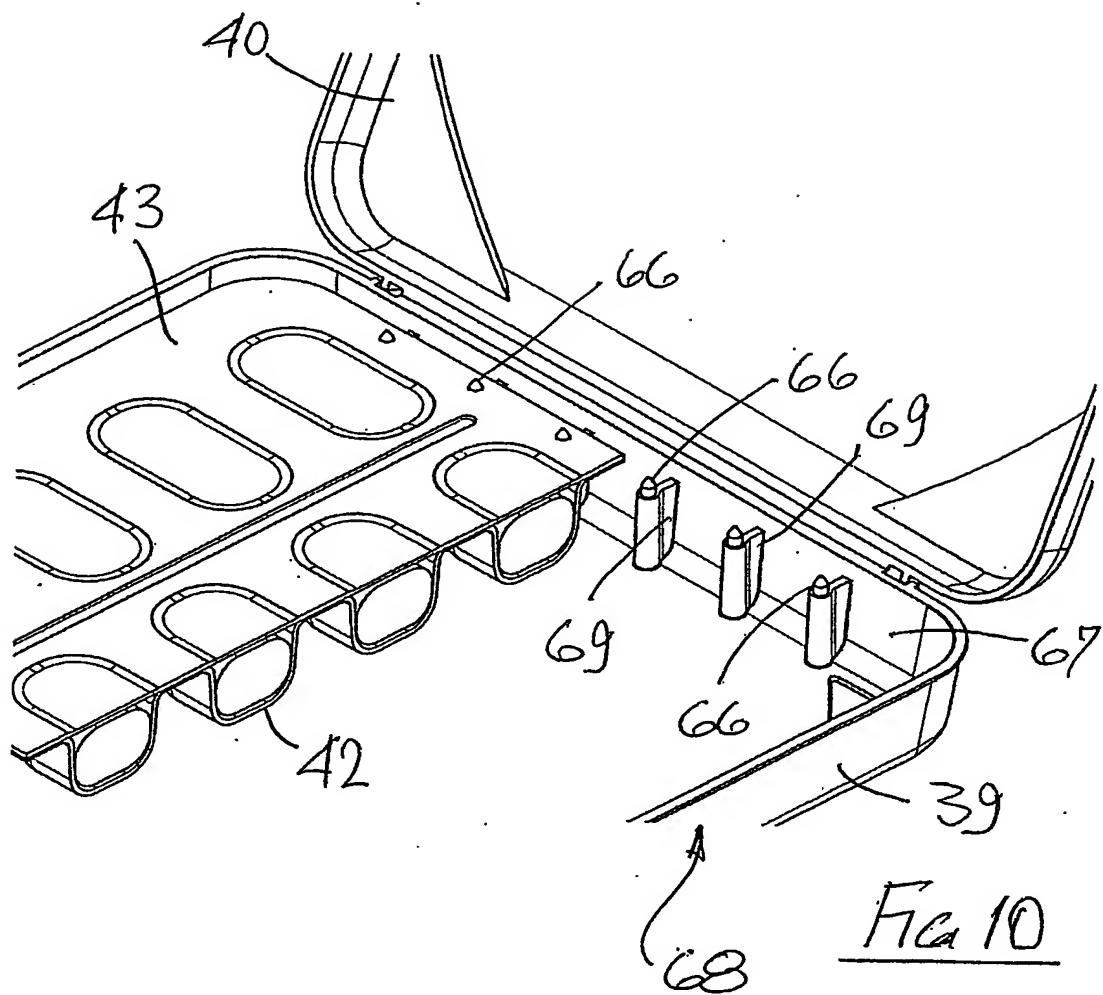


Fig 11A

Fig 11B

Fig 11C

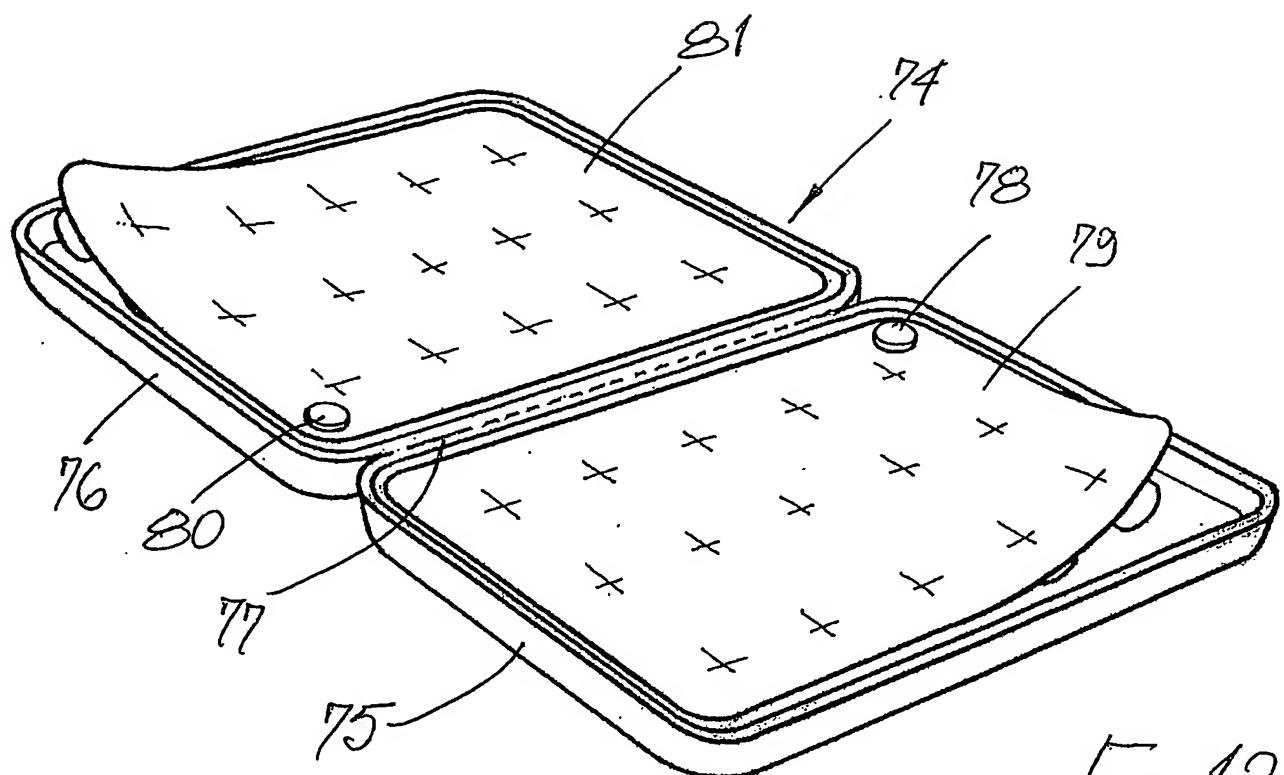


Fig 12

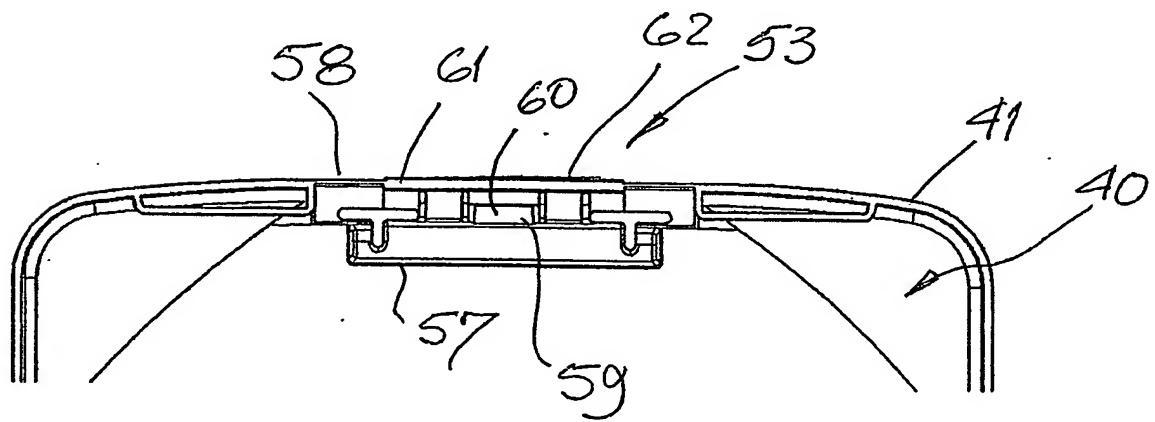


Fig 9A

PACKAGING FOR A BLISTER PACK

This invention relates to packaging for a blister pack carrying a plurality of pills, tablets, capsules or other similar forms of ingestible pharmaceutical products. Such products are for convenience hereinafter referred to simply as "medication pills".

5 A typical blister pack has a plastics material blister sheet formed with a plurality of separate pockets (blisters) in each of which a single medication pill is carried, the blister sheet being bonded to a foil so as to enclose the pills in their respective blisters. The pills may be released from the pack one at a time by pressing on a blister to push the pill and so burst the foil solely in the region
10 of that blister, or by peeling back the foil to expose a pill in a blister.

Blister packs have many advantages as compared to more traditional packaging for medication pills, such as screw-top bottles or other containers. For example, each pill is held separate from the others and may be hermetically sealed in its blister, so reducing the likelihood of contamination or deterioration
15 of the pills. Also, it is easier for a patient to keep track of the ingestion of the pills, especially if it is critical that only a certain number is taken on each day and the pack is marked to show the days on which respective pills are to be taken. Further, patients with manipulative impairment often find it easier to remove pills from the blisters than opening a container, especially if a cap for
20 the container is provided with some kind of child-resistant security device.

A blister pack as supplied to a patient normally is packaged within an outer carton, both to protect the blister pack and also to give a pharmacist and the patient readily accessible information about the product. Though the blister

pack itself may carry some indications as to the kind of medication of the packed pills, there is insufficient room on the blister pack to give much information about the product. As such, in addition to the information on the carton, it is the usual practice to include in a carton for the blister pack a patient information leaflet, giving relevant information to a patient.

5 A patient has to remove the blister pack from its carton in order to release and then take a pill. There is a tendency for a patient not to replace the pack in its packaging once a course of medication has been commenced, so that the blister pack no longer is associated with the information leaflet and the 10 indications on the carton. Worse, if a patient is on more than one course of medication, it can happen that the patient replaces a blister pack in the wrong carton and then mistakenly takes the wrong pills at the wrong times, basing this on the medication identification on the carton, rather than on the blister pack.

There is another problem associated with blister packs. It is very easy 15 for children to remove pills from a blister pack and so it is important that blister packs are kept out of reach of children. Even if a blister pack is still contained within its carton, opening of the carton presents no problem to a typical child who then will have access to the medication.

There are now proposals greatly to increase the security associated with 20 blister packs. Regulations are likely to be introduced which will require a blister pack always to be associated with at least some patient information – and at the very least, a clear indication of the kind of medication contained within the blisters. Further, other regulations are likely to require an increased level of child-resistance, so as to reduce the likelihood of a child being able to release

pills from the blisters in the event that a child gets hold of either the blister pack, or a container for the pack.

The present invention aims at addressing the above problems associated with blister packs and so to permit the continued provision of 5 medication pills in blister packs even if the anticipated regulations are brought into effect.

According to the present invention there is provided packaging for a blister pack containing medication pills, which packaging comprises a container having a tray for receiving the blister pack and a lid hinged to the tray for 10 movement between a closed position where the pack is wholly enclosed within the container and an open position where access may be gained to the pack, a pin carried by one of the tray and the lid to project towards the other of the tray and lid, the pin being configured so that in use a blister pack may be engaged with the pin whereafter removal of the pack from the pin is resisted, thereby 15 retaining the pack within the packaging.

With the packaging of this invention, a blister pack is normally enclosed within a relatively flat container having a tray and lid, the lid being openable to expose the pack. However, the pack is securely held on a pin provided within the container so that the pack cannot with ease be wholly removed from the 20 container and so always will be associated with the container unless a patient deliberately takes steps to free the pack, such as by cutting the pack from an edge margin to the pin. Release of pills can still easily be performed, in view of the flexibility of typical blister packs. The major external areas of the tray and lid may carry labels giving as much information as is required, for example

concerning the kind of medication in the pack, the dosage, contra-indications and so on. In this way, it is highly unlikely that a patient will inadvertently take inappropriate medication through confusion between different blister packs and the cartons for those packs.

5 In addition, the tray and lid of a container may be provided with some kind of child-proof catch mechanism adapted to hold the lid in its closed position until released. Then, even if a young child should get hold of the container, so long as the patient had properly closed it beforehand the likelihood of the child gaining access to the pills within the blisters of the
10 contained pack is greatly reduced.

There are several ways in which a blister pack may be retained on the pin provided within the container. In the preferred form of this invention, the pin is permanently secured internally to a major area of either the tray or the lid, so as to upstand generally perpendicularly from that area and project towards the
15 other of the tray or lid. The pin could extend substantially wholly to the opposed major area when the lid is in its closed position but preferably has a length which is greater than the internal spacing between the major areas of the tray and lid, an aperture being provided in the tray or lid (as appropriate) in opposition to the pin so that the free end of the pin is received in that aperture
20 when the lid is in its closed position.

Conveniently, the pin is provided with at least one barb-like formation, but preferably with a pair of opposed such formations, at or adjacent its free end. Then, by pressing a planar portion of the blister pack on to the pin, the barb-like formations will serve to resist subsequent removal of the pack from

the pin. The pin may have a sharpened free end, to assist the penetration of the pin through the material of the pack, so obviating the need to pre-form a hole of an appropriate size in the pack.

In this preferred form of packaging, and where the free end of the pin is

5 received in an aperture in the lid or tray (as appropriate, depending on which major area carries the pin) the material of the major area around the aperture may be profiled such that placing the blister pack within the open container and then closing the lid pushes the blister pack on to the pin, past the or each barb-like formation on the pin. On subsequently opening the lid, the pack will be

10 securely held on the pin. Thus, no special production step need be taken subsequent to the manufacture of the blister pack containing the pills; it is merely a matter of placing the blister pack in the tray and closing the lid, rather than placing the blister pack in a carton as is performed at the present time.

In an alternative arrangement, the pin may be made of a plastically-deformable material and initially has a length greater than the internal spacing between the major areas of the tray and the lid, when closed. Then, either on moving the lid to its closed position for the first time, or by using a separate tool, the pin will be plastically deformed to reduce its length to the internal spacing and provided that the pin is suitably profiled, at least the free end region of the

20 pin may be expanded so as thereafter to retain on the pin a blister pack previously pressed on to the pin. Alternatively, a hot-forming, a welding or similar process may be used to give an appropriate profile to the free end of the pin for retaining a pack thereon.

As discussed above, the pin is preferably disposed within the container, on the major area of one of the tray or the lid. Another possibility is for the container to be profiled for containing all of the blister pack except for a marginal or corner region thereof, the container having a pair of flanges 5 external to the major areas and between which that pack region is disposed. In this case the pin may be provided on one of those flanges and be received in a hole in the other flange, whereby the pack is trapped between the flanges irrespective of the opening and closing of the packaging.

Yet another possibility is to provide a pin with a barb-like formation at 10 one end thereof and a shoulder partway between the ends of the pin. One of the tray and the lid may have a hole into which the barbed end of the pin may be received essentially irremovably by virtue of the barbs and the other of the tray and lid may have an aperture through which the pin may be passed to engage the barbed end thereof with the hole, when the lid is in its closed 15 position. With this arrangement, the blister pack is placed within the tray, the lid is closed and then the barbed end of the pin is pushed through the aperture, through the blister pack and engaged with the hole; on subsequently opening the lid, the pack is trapped in place by the shoulder on the pin.

The packaging may be modified in order to allow two blister packs to be 20 contained therein, by providing a first pin on the tray and a second pin on the lid. Each of the two pins may be similarly configured but disposed at spaced-apart locations so that there will be no interference between the pins when the lid is closed. Typically, the pins will be disposed in opposed corner regions of the tray or lid.

By way of example only, certain specific embodiments of blister pack packaging of this invention will now be described in detail, reference being made to the accompanying drawings in which:-

5 Figure 1 is an isometric view of a first embodiment, with the lid in its closed position;

Figure 2 is an isometric view of the first embodiment, but with the lid open;

Figure 3 is a detail view on a corner region of a second embodiment of blister packaging;

10 Figures 4A and 4B illustrate the entrapment of a blister pack with the second embodiment of packaging;

Figure 5 is an isometric view of a third embodiment, with the lid in its open position;

15 Figure 6 is an isometric view of the third embodiment, but with the lid closed;

Figures 7A and 7B show the blister pack entrapment in the third embodiment;

Figure 8 is a cross-section through the third embodiment, with the lid slightly open;

20 Figure 9 is a detail view on the catch mechanism employed in the third embodiment;

Figure 9A is a view on the underside of the lid of the third embodiment, showing the catch mechanism;

Figure 10 is a detail view on part of the third embodiment, but showing an alternative arrangement of pins for retaining a blister pack;

Figures 11A, 11B and 11C illustrate the entrapment of a blister pack with the alternative arrangement of the third embodiment of packaging; and

5 Figure 12 illustrates a fourth embodiment, adapted to hold two blister packs.

Referring initially to Figures 1 and 2, there is shown a relatively simple first embodiment of this invention, adapted to entrap a blister pack 15 within a container 16 comprising a tray 17 and a lid 18 hinged together along one edge

10 19. The tray and lid typically are a one-piece plastics moulding, produced for example using an injection-moulding technique, and so the container is relatively cheap to manufacture provided sufficiently large numbers are produced.

The tray 17 has a major area of approximately rectangular shape and 15 around which upstand side walls 20, to define a space slightly larger than the pack 15 to be contained, except for a corner region to be discussed below. The lid is similarly profiled and has a major area 21 from which depend side walls 22 which engage with the side walls 20 of the tray, when the lid is in its closed position as shown in Figure 1. The side wall of the tray opposed to the hinged 20 edge 19 is provided with one part 23 of a catch mechanism, this part defining a slot 24 within which is received a tab 25 provided on the corresponding side wall of the lid. The tab may have a small outwardly-directed projection which may snap behind the material defining the slot 24, so as to resist opening

unless the tab is depressed inwardly of the container at the same time as an opening force is applied to the lid.

In one corner region 27 of the container, the side walls are profiled so that there are formed flanges 28,29 on the tray and lid respectively, in the plane 5 of the free edges of the side walls. The flange 28 of the tray is provided with a through-hole (not shown) and the flange 29 of the lid has a pin 30 which may be received in the hole of the flange 28 when the lid is closed. The pin may be profiled so as to be a snap-fit in the hole and to resist removal from the hole once pressed fully home therein. The corner 31 between the lid and the flange 10 29 is of weakened cross-section, such that the flange 29 may be broken away from the lid.

In use, the blister pack 15 is provided with an opening in its corner region and then is dropped in the tray with the hole therein more or less aligned with the hole in flange 28. Closing of the lid will then push the pin 30 through the 15 blister pack and into the hole in the tray flange 28, so trapping the blister pack between the flanges. The lid will be held closed by its tab 25 but on subsequent deliberate opening of the pack, the weakened corner 31 will break away from the lid, so leaving the lid flange 29 overlying the tray flange 28, as shown in Figure 2. In the alternative, the lid flange 29 may be broken away 20 from the lid during assembly, to obviate inadvertent removal of the lid flange from the tray flange, by a patient.

The profile of the pin could be modified so as to pierce the membrane of the blister pack, and eliminate the need to pre-form a hole therethrough. Other possibilities include hot or cold forming of the pin to trap the blister or even the

use of adhesives or other bonding techniques to ensure the pin remains engaged with the tray flange 29, on subsequent opening of the lid.

Figures 3 and 4 illustrate an alternative entrapment technique for a container as shown in Figures 1 and 2. In this embodiment, the side walls are 5 similarly formed in all four corners and consequently no flanges 28 and 29 are provided. Rather, in a corner region of the tray there is formed a bar 33 from which projects a pointed pin 34 of generally rectangular cross-sectional shape, the pin having opposed barbs 35 projecting from opposed faces of the pin. The free end of the pin lies generally in the plane of the upper edges of the side 10 walls of the tray. The lid is provided with a tubular boss 36 projecting internally in opposition to the pin 34, into which the barbed end of the pin will be received on closing the lid.

In this arrangement, a blister pack is simply placed within the tray 17 so that a corner region of the pack overlies the pin 34. Then, on closing the lid the 15 boss 36 will bear on the pack, as shown in Figure 4A, and press the pack down on to the pin, past the barbs 35. On subsequently opening the container as shown in Figure 4B, the pack will be securely retained on the pin.

Figures 5 to 9 show a third embodiment of this invention, as comprising a generally rectangular tray 38 having upstanding side walls 39 and a lid 40 with 20 depending side walls 41 of a sufficient depth to accommodate the blisters 42 of a blister pack 43 retained within the packaging. As with the first embodiment, the packaging is a one-piece plastic moulding with the lid hinged to the tray along a side edge 44.

A corner region of the lid is formed with an opening 45 in which is disposed the enlarged head 46 of a pin 47, the pin being held by four (or two) frangible nibs. The opposed end 48 of the pin is barbed and shoulder 49 is formed adjacent the barbed end, by the enlarged head 46. The major area of 5 the tray 38 has an aperture 50 in opposition to the opening 45 in the lid, the aperture having a lead-in for the barbed end 48 of the pin 47 and also an abutment surface 51 within the aperture. As an alternative, the pin 47 could be separately formed and carried in a through-hole 45 in the lid.

In use, the blister pack 43 is placed on the tray 38 and the lid 40 is 10 closed, as shown in Figure 7A. Pressure is then applied to the enlarged head 46 of the pin so as to break the frangible nibs and push the barbed end 48 of the pin through a corner region of the blister pack and into the aperture 50, until the barbs of the pin engage behind the abutment surface 51 of the aperture, as shown in Figure 7B. Subsequent opening of the lid 40 will leave the pin in 15 aperture 50, with the blister pack trapped by the shoulder 49 of the pin.

In order to retain the lid 40 in its closed position, the packaging of Figures 5 and 6 is provided with a child-resistant catch mechanism 53 shown in greater detail in Figures 8, 9 and 9A. The tray 38 has an outwardly-projecting flange 54, from which upstands a tab 55 formed with a slot 56, for part of the 20 length of the tab. The lid 40 has, in its region which lies adjacent the flange 54, a pair of spaced U-shaped carriers 57 between which is supported a wall element 58, separated at its ends from the side walls 41 of the lid. The carriers 57 support a catch member 59 receivable within the slot 56, as the lid is closed. The catch member is profiled at 60 in order to facilitate inward springing of the

carriers and so to permit the catch member 59 to ride over the tab 55 and then spring outwardly into the slot 56, as the lid becomes fully closed. In this position, the outer edge 61 of the wall element 58 engages the upper surface of the flange 54, so defining the fully closed position.

5 In order to open the container, the ribbed part 62 of the wall element 58 must be pressed inwardly sufficiently to free catch member 59 from the slot 56 in the tab 55, at the same time as applying an opening movement to the lid 40. An adult will normally perform this action by spanning the lid with one hand, simultaneously pressing on the nibbed part 62 and the opposed edge of the lid, 10 and hinging the lid away from the base while holding the base with the other hand. A young child will find the required manual dexterity difficult to perform, because of the required combined action coupled with an insufficient hand-span.

15 In this embodiment, recesses 64 are provided in the corner regions of the lid, to engage with feet (not shown) formed on the lower surface of the tray. This will facilitate stable stacking of a number of the containers, for example during transport and storage prior to dispensing to patients.

Figures 10 and 11 show an alternative method for entrapping a blister pack, to replace the pin arrangement of Figures 7A and 7B of the third 20 embodiment. In this embodiment, a row of pins 66 is provided along a side wall 67 of the tray 68, each pin being carried on a web 69 so as to project towards the lid, when closed. Each pin has a sharp tip able to penetrate the material of the blister pack and once this has been achieved, the free end of the pin is

staked over in a suitable manner so as thereafter to retain the blister pack on the pin.

The pin could be made of a plastically-deformable material, a press being employed to push the blister pack on to the pin. Such a press may have 5 a boss 70 defining a blind bore 71, as shown in Figures 11A, so that on pushing the boss over the pin, the blister pack will be pressed down on to the pin, as shown in Figure 11B. Continued pressure on the boss 70 will engage the end of the pin with the blind end of the bore and then deform the end of the pin as shown in Figure 11C, thereby to retain the blister pack thereon.

10 As an alternative to the cold-forming described above, the deformation of the pin as shown in Figure 11C could be achieved by a hot-forming process or by a welding process, for example fusing a head on to the end of the pin.

Figure 12 shows a further package 74 where two blister packs are accommodated, one in the tray 75 and one in the lid 76. As with the previous 15 embodiments, the tray and lid comprise a one-piece plastics moulding hinged together along one edge 77. At one end of that edge the tray 75 is provided with a pin 78 adapted to retain a blister pack 79 thereon and at the other end of the edge 77 the lid 76 is provided with a pin 80 adapted to retain a second blister pack 81 thereon. In this embodiment, the pins 78 and 80 may be 20 generally similar to those of Figures 10 and 11 and so may be provided with a head to retain a blister pack in the same manner as has been described with reference to Figures 11A, 11B and 11C.

In other respects, this arrangement is similar to the third embodiment of Figures 5 and 6 and so will not be described in further detail here.

CLAIMS

1. Packaging for a blister pack containing medication pills, which packaging comprises a container having a tray for receiving the blister pack and a lid hinged to the tray for movement between a closed position where the pack is wholly enclosed within the container and an open position where access may be gained to the pack, a pin carried by one of the tray and the lid to project towards the other of the tray and lid, the pin being configured so that in use a blister pack may be engaged with the pin whereafter removal of the pack from the pin is resisted thereby retaining the pack within the packaging.
2. Packaging for a blister pack as claimed in claim 1, wherein the pin is disposed internally of the container and is permanently secured to a major area of one of the container tray and lid.
3. Packaging for a blister pack as claimed in claim 2, wherein the pin extends substantially wholly to the other of the tray or lid when the lid is in its closed position.
4. Packaging for a blister pack as claimed in claim 2, wherein the length of the pin is greater than the internal spacing between the major areas of the tray and lid and the other of the tray and lid has an aperture within which the free end of the pin is received when the lid is in its closed position.
5. Packaging for a blister pack as claimed in any of claims 2 to 4, wherein the pin is provided with at least one barb-like formation at or adjacent its free end, to retain a blister pack thereon once pressed on to the pin.
6. Packaging for a blister pack as claimed in claim 5, wherein the or each pin is provided with a pair of barb-like formations on opposed sides of the pin.

7. Packaging as claimed in claim 4 and in one of claim 5 or claim 6, wherein the aperture is profiled so that on placing a pack within the container when the lid is in its open position and then closing the lid, the free end of the pin entering the aperture presses the pack on to the pin, whereafter on opening the pack, the pack is retained on the pin.

5

8. Packaging for a blister pack as claimed in any of claims 2 to 4, wherein the pin is of a plastically-deformable material and initially has a length greater than the internal spacing between the major areas of the tray and lid, and on moving the lid to its closed position for the first time plastically deforms at least the free end region of the pin so retaining a pack previously pressed on to the pin.

10

9. Packaging for a blister pack as claimed in claim 1, wherein the pin has a barb-like formation at one end thereof and a shoulder part-way between the ends of the pin, one of the tray and the lid having a hole into which the barbed end of the pin may be irremovably received and the other of the tray and lid having an aperture through which the pin may be passed to engage the barbed end with said hole when the lid is in its closed position, so trapping a blister pack within the container between said one of the tray and lid and the shoulder on the pin.

15

20 10. Packaging for a blister pack as claimed in any of claims 2 to 8, wherein the other of the tray and lid carries a second pin which projects towards the one of the tray and lid in a location remote from the location of the first-mentioned pin, whereby a second blister pack may be contained and retained within the packaging.

11. Packaging for a blister pack as claimed in any of the preceding claims, wherein the pin is provided in a corner region of the tray, to be engaged by a corner portion of the blister pack.
12. Packaging for a blister pack as claimed in any of claims 2 to 8, wherein 5 said one of the tray and lid carries a plurality of similar pins each configured to be engaged with a blister pack and resist removal of a pack therefrom.
13. Packaging for a blister pack as claimed in claim 12, wherein the plurality of pins are aligned in a row and are disposed along an edge of the tray, to be engaged with an edge margin of a pack.
- 10 14. Packaging for a blister pack as claimed in any of the preceding claims, wherein the pin is of generally rectangular cross-sectional shape.
15. Packaging for a blister pack as claimed in claim 1, wherein the tray has a first flange external to the major area of the tray and there is a second flange adapted to overlie the first flange, the pin being provided on one of the flanges and the other flange having a hole in which the pin may be received, the tray and lid being profiled so that when the greater part of a blister pack is located between the tray and lid, an edge portion of the pack lies between the first and second flanges and is retained there by the pin.
- 20 16. Packaging for a blister pack as claimed in claim 15, wherein the second flange is formed as a part of the lid, but is connected thereto by a frangible joint whereby the lid may be opened leaving the two flanges interengaged by the pin following breaking of the joint.
17. Packaging for a blister pack as claimed in any of the preceding claims, wherein a catch mechanism is provided to hold the lid in its closed position.

18. Packaging for a blister pack as claimed in claim 17, wherein the catch mechanism has child-resistant properties.
19. Packaging for a blister pack containing medication pills and substantially as hereinbefore described, with reference to the accompanying drawings.